

IN THE CLAIMS

1. (Canceled) A mucoadhesive composition suitable for a mucosal or transmucosal vaginal delivery of an anti-migraine or antinausea drug, said composition comprising from about 0.001 to about 3000 mg of the antimigraine or antinausea drug, from about 30 to about 95% of a lipophilic or hydrophilic carrier, from about 0.1 to about 25% of a mucoadhesive agent and from about 5 to about 30% of a sorption promoter.

2. (Canceled) The composition of claim 1 wherein said mucoadhesive agent is hydroxypropyl methylcellulose, a cellulose derivative, a natural gum, alginate or pectin, present in from about 1.5 to about 15%, by weight, wherein said sorption promoter is ethoxydiglycol, polyethylene glycol caprylic/capric glycerides, a glycol derivative with oleic acid esters of propylene glycol and glycerol or interesterified stone oil present in from about 2 to about 30%, by weight, wherein the lipophilic carrier is a saturated mono-, di- or triglyceride of fatty acids having carbon chain of from 8 to 18 carbons, or a mixture thereof, present from about 30 to about 95%, by weight, wherein the hydrophilic carrier is a polyethylene glycols (PEG) of a molecular weight between about 200 and 8000, or a derivative or mixture thereof, PEG 6000/PEG 1500, PEG 6000/PEG 1500/PEG 400, or PEG 6000/PEG 400, or PEG 8000/PEG 1500, present from about 30 to about 95%, by weight.

3. (Canceled) The composition of claim 2 wherein said mucoadhesive agent is hydroxypropyl methylcellulose present in

from about 1.5 to about 5%, wherein said sorption promoter is ethoxydiglycol present in from about 15%, wherein said lipophilic carrier is the saturated mono-, di- or triglyceride of fatty acids having carbon chain of from 8 to 18 carbons and a mixture thereof, present from about 65 to about 70%, and wherein said composition further comprises from about 1 to 1000 mg of antimigraine or antinausea drug.

4. (Canceled) The composition of claim 3 wherein said antimigraine drug is selected from the group of compounds consisting of ergotamine, dihydroergotamine, ergostine, butalbital, phenobarbital, acetaminophen, diclofenac sodium, ketoprofen, ketorolac, ibuprofen, piroxicam, naproxen, acetylsalicylic acid, flurbiprofen, tolfenamic acid, butorphanol, meperidine, methadone, sumatriptan, naratriptan, rizatriptan, zolmitriptan, almotriptan, eletriptan, dexamethasone, hydrocortisone, isometheptene, chlorpromazine, diazepam, droperidol, valproic acid, gabapentin, topiramate and divalproex sodium, and wherein said antinausea drug is selected from the group consisting of metoclopramide, prochlorperazine, domperidone, ondansetron, tropisetron, dolasetron, nabilone, dronabinol, levonantradol, aprepitant, cyclizine, promethazine and combination thereof.

5. (Canceled) The composition of claim 4 wherein said antimigraine or antinausea drug is ergotamine administered in a range from about 15 to about 300 mg/day, diclofenac sodium administered in a range from about 100 to about 500 mg/day, sumatriptan administered in a range from about 20 to 500 mg/day, zolmitriptan administered in a range from about 10 to about 420

mg/day, naratriptan administered in a range from about 10 to about 350 mg/day, metoclopramide administered in a range from about 20 to 120 mg/dose, prochlorperazine administered in a range from about 25 to 150 mg/dose, ondansetron administered in a range from about 30 to 210 mg/dose, dronabinol administered in a range from about 10 to 50 mg/day, and promethazine administered from about 12 to about 80 mg/dose.

6. (Currently amended) A method for treatment of migraine and associated headache, nausea or vomiting associated with chemotherapy, radiotherapy, surgery, pregnancy or menopause, said method comprising a step:

administering to a female subject in need of such treatment vaginally a mucoadhesive composition comprising from about 0.001 to about 3000 mg of the antimigraine or antinausea drug, from about 30 to about 95% of a lipophilic or hydrophilic carrier, from about 0.1 to about 25% of a mucoadhesive agent and from about 5 to about 30% of a sorption promoter,

wherein said antimigraine drug is selected from the group of compounds consisting of ergotamine, dihydroergotamine, ergostine, butalbital, phenobarbital, acetaminophen, diclofenac sodium, ketoprofen, ketorolac, ibuprofen, piroxicam ~~prioxicam~~, naproxen, ~~acetylsalicylic~~ acetylsalicylic acid, flurbiprofen, tolfenamic acid, butorphanol, meperidine, methadone, sumatriptan, naratriptan, razatriptan, zolmitriptan, almotriptan, eletriptan, dexamethasone, hydrocortisone, isometheptene, chlorpromazine, diazepam, droperidol, valproic acid, gabapentin, topiramate and divalproex sodium, and wherein said antinausea drug is selected from the group consisting of metoclopramide, prochlorperazine, domperidone, ondansetron, tropisetron, dolasetron, nabilone,

dronabinol, levonantradol, aprepitant, cyclizine, promethazine, and a combination thereof.

7. (Original) The method of claim 6 wherein said composition is formulated and administered vaginally as a cream, lotion, foam, film, suppository, tablet, microparticle, nanoparticle, capsule, capsule containing microparticles, emulsion, liposomal suspension fluid, a bioadhesive system or microemulsion.

8. (Currently amended) The method of claim 7 wherein said method additionally comprises step of inserting into vagina an intravaginal device incorporated with said composition, wherein said composition is formulated as a cream, lotion, foam, film, suppository, tablet, microparticle, nanoparticle, capsule, capsule containing microparticles, emulsion, liposomal suspension fluid, a bioadhesive system or microemulsion ~~is incorporated into an intravaginal device and said device is inserted vaginally.~~

9. (Currently amended) The method of claim 7 [[8]] wherein said composition is administered at the onset of the migraine or during nausea.

10. (Currently amended) The method of claim 9 for treatment of migraine wherein said treatment comprises administration of a composition comprising ergotamine from about 15 to about 300 mg/day, diclofenac sodium from about 100 to about 500 mg/day, sumatriptan from about 20 to 500 mg/day, zolmitriptan from about 10 to about 420 mg/day, almotriptan from about 20-500 mg/day or naratriptan from about 10 to about 350 mg/day.

11. (Original) The method of claim 9 for treatment of nausea wherein said treatment comprises administration of a composition comprising metoclopramide from about 20 to 120 mg/dose, prochlorperazine from about 25 to 150 mg/dose, ondansetron from about 30 to 210 mg/dose, dronabinol from about 10 to 50 mg/day or promethazine from about 12 to about 80 mg/dose.

12. (Currently amended) The method of claim 8 wherein said intravaginal device is a tampon, tampon-like device, pessary, ring, tablet, capsule, pad, patch, suppository, cup, sponge, strip, foam or intravaginal iontophoretic system, and wherein said antimigraine or antinausea drug is released from said composition incorporated into form said device.

13. (Currently amended) The method of claim 12 wherein said device is the tampon-like device inserted into the vagina at the onset of the migraine or during nausea.

14. (Currently amended) The method of claim ~~[[13]]~~ wherein said device is the tampon inserted into the vagina at the onset of the migraine or during nausea.

15. (Currently amended) The method of claim ~~7~~ ~~14~~ for treatment of migraine wherein said treatment comprises administration of a composition comprising ergotamine from about 15 to about 300 mg/day, diclofenac sodium from about 100 to about 500 mg/day, sumatriptan from about 20 to 500 mg/day, zolmitriptan from about 10 to about 420 mg/day, almotriptan from about 20 to about 500 mg/day or naratriptan from about 10 to about 350 mg/day or wherein said composition is incorporated into an intravaginal

device and said treatment comprises insertion of said intravaginal device into vagina.

16. (Currently amended) The method of claim 7 ~~14~~ for treatment of nausea wherein said treatment comprises administration of a composition comprising metoclopramide from about 20 to 120 mg/dose, prochlorperazine from about 25 to 150 mg/dose, ondansetron from about 30 to 210 mg/dose, dronabinol from about 10 to 50 mg/day or promethazine from about 12 to about 80 mg/dose or wherein said composition is incorporated into an intravaginal device and said treatment comprises insertion of said intravaginal device into vagina.

17. (Canceled) An intravaginal device for mucosal and transmucosal delivery of an antimigraine or antinausea drug

wherein said device is a tampon, tampon-like device, pessary, patch, ring, tablet, pad, suppository, sponge, film, foam, strip or intravaginal iontophoretic system incorporated with a mucoadhesive composition comprising antimigraine drug, antinausea drug or a combination thereof;

wherein said device is incorporated with a mucoadhesive composition comprising from about 0.001 to about 3000 mg of the antimigraine or antinausea drug, from about 30 to about 95% of a lipophilic or hydrophilic carrier, from about 0.1 to about 25% of a mucoadhesive agent and from about 5 to about 30% of a sorption promoter,

wherein said antimigraine drug is selected from the group of compounds consisting of ergotamine, dihydroergotamine, ergostine, butalbital, phenobarbital, acetaminophen, diclofenac sodium, ketoprofen, ketorolac, ibuprofen, piroxicam, naproxen,

acetylsalicylic acid, flurbiprofen, tolfenamic acid, butorphanol, meperidine, methadone, sumatriptan, naratriptan, razatriptan, zolmitriptan, almotriptan, eletriptan, dexamethasone, hydrocortisone, isometheptene, chlorpromazine, diazepam, droperidol, valproic acid, gabapentin, topiramate and divalproex sodium, and wherein said antinausea drug is selected from the group consisting of metoclopramide, prochlorperazine, domperidone, ondansetron, tropisetron, dolasetron, nabilone, dronabinol, levonantradol, aprepitant, cyclizine, and promethazine, each alone or in combination with an another pharmaceutical agent or a pharmaceutically acceptable excipient; and

wherein said antimigraine or antinausea drug is released from said device following the insertion of the device into vagina.

18. (Canceled) The device of claim 17 wherein the device is the tampon and said composition is incorporated withing the tampon.

19. (Canceled) The device of claim 17 wherein the device is the tampon and said composition is applied as a coating on the surface of the tampon.

20. (Canceled) The device of claim 17 wherein the device is the tampon and said composition is formulated as a foam or film and is either incorporated into the tampon or applied to the surface of the tampon.

21. (New) The method of claim 6 wherein said mucoadhesive agent is hydroxypropyl methylcellulose, a cellulose derivative, a natural gum, alginate or pectin, present in from about 1.5 to about 15%, by weight, wherein said sorption promoter is ethoxydiglycol, polyethylene glycol caprylic/capric glycerides, a glycol derivative with oleic acid esters of propylene glycol and glycerol or interesterified stone oil present in from about 2 to about 30%, by weight, wherein said lipophilic carrier is a saturated mono-, di- or triglyceride of fatty acids having carbon chain of from 8 to 18 carbons, or a mixture thereof, present from about 30 to about 95%, by weight, wherein the hydrophilic carrier is polyethylene oxide, polyethylene glycol (PEG) of a molecular weight between about 200 and 8000, or a derivative or mixture thereof, PEG 6000/PEG 1500, PEG 6000/PEG 1500/PEG 400, or PEG 6000/PEG 400, or PEG 8000/PEG 1500, present from about 30 to about 95%, by weight.

22. (New) The method of claim 21 wherein said mucoadhesive agent is hydroxypropyl methylcellulose present in from about 1.5 to about 60%, wherein said sorption promoter is ethoxydiglycol present in from about 10 to about 15%, wherein said hydrophilic carrier is polyethylene oxide present from about 6 to about 30%, and wherein said anti-migraine or anti-nausea drug is present from about 1 to 1000 mg.

23. (New) The method claim 21 wherein said antimigraine or antinausea drug is ergotamine administered in a range from about 15 to about 300 mg/day, diclofenac sodium administered in a range from about 100 to about 500 mg/day, almotriptan administered in a range from about sumatriptan administered in a range from about



20 to 500 mg/day, almotriptan from about 20 to about 500 mg/day, zolmitriptan administered in a range from about 10 to about 420 mg/day, naratriptan administered in a range from about 10 to about 350 mg/day, metoclopramide administered in a range from about 20 to 120 mg/dose, prochlorperazine administered in a range from about 25 to 150 mg/dose, ondansetron administered in a range from about 30 to 210 mg/dose, dronabinol administered in a range from about 10 to 50 mg/day, and promethazine administered from about 12 to about 80 mg/dose.

24. (New) The method claim 22 wherein said anti-migraine drug is sumatriptan.

25. (New) The method claim 22 wherein said anti-migraine drug is almotriptan.

26. (New) The method claim 22 wherein said composition is formulated as the film.

27. (New) The method claim 22 wherein said mucoadhesive agent is hydroxypropyl methylcellulose.

28. (New) The method of claim 22 wherein said sorption promoter is triethanolamine.

29. (New) The method of claim 22 wherein said hydrophilic carrier is polyethylene oxide.

30. (New) The method of claim 22 wherein said antimigraine drug is almotriptan, said mucoadhesive agent is hydroxypropyl

methycellulose, said hydrophilic carrier is polyethylene oxide and said sorption promoter is triethanolamine.